Questions and Answers About the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial

1. What is the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial?

The Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial, or PLCO Trial, is a large-scale study to determine if certain tests will reduce the number of deaths from these cancers. Sponsored by the National Cancer Institute (NCI), the United States Government's lead agency for cancer research, the study will involve 148,000 men and women ages 55 through 74 at medical facilities in 10 geographic areas across the United States.

2. What is a clinical trial?

A clinical trial is a research study conducted with people. There are many types of clinical trials. They range from studies to prevent, detect, diagnose, and treat a disease, to studies of the psychological impact of the disease and ways to improve a participant's comfort and quality of life.

3. What is a screening test?

A screening test is a type of examination, done by a health professional, that may find cancer before it causes symptoms or pain. Most people who are tested will not have cancer.

4. Why are screening tests for these cancers being studied?

Together, prostate, lung, colorectal, and ovarian cancers account for nearly half of all cancers diagnosed as well as cancer deaths in the United States each year. The tests being studied may detect these cancers before symptoms develop, but whether treatment at this stage will reduce the chance of dying from the diseases is unknown.

5. Doesn't early detection of cancer offer a better chance for effective treatment and survival?

Some medical experts believe that the earlier prostate, lung, colorectal, and ovarian cancers are detected, the better the chance that treatment will extend or save lives. However, early detection does not necessarily mean that a patient's life is extended. The PLCO Trial is designed to help answer this question.

6. What screening tests are being studied?

Different tests are being studied for each type of cancer.

For **prostate cancer**, men will have a digital rectal exam and a blood test for prostate-specific antigen (known as PSA).

For **lung cancer**, men and women will receive a regular chest x-ray.

For **colorectal cancer**, men and women will be screened with a lighted instrument called a flexible sigmoidoscope that lets health professionals see inside the rectum and the lower part of the colon.

For **ovarian cancer**, women will have a physical exam of the ovaries, a blood test for the tumor marker known as CA-125, and an ultrasound test called transvaginal ultrasound.

7. What is a digital rectal exam?

A digital rectal exam, or DRE, is a physical exam in which a health professional feels for abnormalities in a man's prostate gland. Because the prostate is located near the rectum, a clinician can feel it by inserting a gloved finger into the rectum.

8. What is prostate-specific antigen?

Prostate-specific antigen, or PSA, is a protein produced by both normal and cancerous prostate cells. PSA levels are frequently elevated in the blood of men with prostate cancer and certain benign (not cancerous) conditions. The U.S. Food and Drug Administration (FDA) has approved a PSA test for **monitoring** prostate cancer patients after treatment and for use in conjunction with a digital rectal exam to help **detect** prostate cancer in men age 50 or older.

9. What is a flexible sigmoidoscopy examination?

Using a lighted viewing tube called a sigmoidoscope, which is gently inserted in the rectum, a clinician can look at the inside lining of the lower part of the intestine (the colon and rectum). Polyps (small noncancerous growths that often precede cancer) and small cancers can be seen in this way.

10. What is CA-125?

CA-125 is a protein produced by a variety of cells, including some ovarian cancer cells. Levels of CA-125 in the blood may go up in women with ovarian cancer. High levels of CA-125 can also occur when other cancers are present, and sometimes when benign conditions are present. The CA-125 blood test is approved by the FDA to monitor patients with ovarian cancer, but is considered experimental as a screening test.

11. What is transvaginal ultrasound?

Transvaginal ultrasound produces an image of the ovaries using a tampon-sized probe inserted into the vagina. The pattern of sound wave echoes produced creates a picture, known as a sonogram, which is shown on a monitor like a TV screen. Because healthy tissues, fluid-filled cysts, and cancer can produce different echoes, the test is potentially useful in detecting ovarian diseases.

12. Who is eligible to participate in the PLCO Trial?

Doctors expect to enroll 148,000 men and women between the ages of 55 and 74 in the trial at 10 medical centers across the country. These volunteers must not have any of the cancers for which they might be screened in the study, although a diagnosis of other cancers may not exclude their participation.

Men participating in the Prostate Cancer Prevention Trial, who are taking either the drug finasteride (Proscar) or a placebo to assess the drug's effect on the prevention of prostate cancer, are not eligible to participate in the PLCO Trial. Men taking finasteride for any reason are not eligible for the PLCO Trial.

Women participating in the Breast Cancer Prevention Trial, who are at increased risk of breast cancer and are taking either tamoxifen (Nolvadex) or a placebo to assess the drug's ability to prevent the disease, are not eligible to participate in the PLCO Trial.

13. Why are individuals ages 55 through 74 the only people eligible for this study?

Cancer occurs more often as people grow older. Most cancers (79 percent) occur in people who are age 55 and older. Because risk for the disease is greater in older persons, they are the most appropriate population to study.

14. Will every participant have every test?

No. The men and women who participate in the PLCO Trial will be randomized (selected by chance) to have either the tests being studied (intervention group) or undergo the usual health care their doctors provide (control group).

15. Why do only half of the study participants receive the tests being studied?

The benefits of the tests being studied are unknown, and they may not provide any advantage to the participants. By comparing the number of cancers diagnosed and the number of cancer deaths in the intervention and control groups, the researchers will be able to determine the potential benefit of the tests under study.

Members of the control group who continue to receive "usual care" from their regular health care providers are not screened at PLCO Trial medical centers, but they will be asked about their personal and family history of cancer and other medical questions. This information is part of the comparison between the groups and will be used to learn more about risks for these diseases. Although they are not having the tests being studied, their participation is vital to the trial.

16. How much will it cost to participate?

There will be no charge to participants for the screening tests being evaluated. Other medical care costs, such as doctor visits, are not covered because they are part of routine care.

17. What if cancer is found?

Results of the PLCO Trial tests are sent to the participants and their physicians as soon as they become available. If there are any abnormal test results, the participant will be referred to a physician of his/her choice for diagnostic followup tests. The costs of diagnostic tests and treatments are not covered in the study because they are part of routine medical care.

18. How often will the tests be conducted?

The intervention group will have the tests at the initial visit and once every year for the next 3 years, except for the sigmoidoscopy exam, which will be performed only twice—during the initial visit and during the third year of the trial. The researchers will be in contact with the participants for at least 10 years from the time they enter the study. Participation is voluntary and participants may withdraw from the study at any time.

The researchers will regularly monitor the information received from the participants and the tests conducted. If a benefit from a particular test is seen, that portion of the study may be stopped so the test can be made available to the general public. Also, if there is a health risk found from administering a test, that part of the study will be modified or stopped.

19. Are there risks from the tests being studied?

All medical procedures carry some risk. Even though the potential risks from these tests are minimal, such risks will be fully explained, and information about them is included in a written consent form that each participant signs before enrolling in the trial.

20. Why is NCI testing digital rectal examination and sigmoidoscopy when the tests are already recommended for screening?

The values of the digital rectal exam in screening for prostate cancer and the sigmoidoscopy exam in screening for colorectal cancer are not well documented. The PLCO Trial will provide vital information on whether use of these exams decreases the number of deaths caused by these cancers.

21. How can a person enroll in the PLCO Trial?

Men and women who are interested in participating in the PLCO Trial should contact the center nearest to them. Locations of the centers can be obtained by calling the NCI's Cancer Information Service at 1–800–4–CANCER (1–800–422–6237). In addition, a complete list of centers is found on the following pages.

22. Is there information about the trial on the World Wide Web (Internet)?

Information about the PLCO Trial can be found at the following address: http://www.dcpc.nci.nih.gov/PLCO/Default.html on the World Wide Web.

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<u>Sources of National Cancer Institute Information</u>

Cancer Information Service
Toll-free: 1–800–4–CANCER (1–800–422–6237)
TTY (for deaf and hard of hearing callers): 1–800–332–8615

NCI Online
Internet
Use http://www.cancer.gov to reach NCI's Web site.

CancerMail Service
To obtain a contents list, send e-mail to cancermail@icicc.nci.nih.gov with the word "help" in the body of the message.

CancerFax® fax on demand service
Dial 301–402–5874 and listen to recorded instructions.

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